



4150-05-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS-OS-20883-30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments to OIRA_submission@omb.eop.gov or via facsimile to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, Information.CollectionClearance@hhs.gov or (202) 690-6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document

identifier HHS-OS-0990-new 30D for reference.

Information Collection Request Title: Tissue and Organ Donor epidemiology Study (TODES)

Abstract: This Study is a request for a new data collection OMB Number: 0990-new TODES is being conducted in order to better understand the impact of donor screening and selection procedures, and to determine the extent of donor-donation level data that are collected for organ and tissue (including ocular) donors. The data that are obtained from Organ Procurement Organizations (OPOs) and Eye Banks will provide a better characterization of the deceased donor pool; information regarding data management and storage practices; and a measure of the degree of standardization of data collected by various organizations across the U.S. TODES may provide better estimates of the risk of HIV, HBV and HCV infections associated with organ and tissue transplantation and the potential for disease transmission; illustrate differences in laboratory screening methods and the impact of protocol variations; and serve as a pilot for future studies. This retrospective study will provide a framework for future, prospective studies of organ and tissue donors that could inform policy decisions regarding donor qualification procedures and, potentially, increase the donor pool.

Need and Proposed Use of the Information: A workshop in June 2005 (“Preventing Organ and Tissue Allograft-Transmitted Infection: Priorities for Public Health Intervention”) identified gaps in organ and tissue safety in the United States. Participants developed a series of allograft safety initiatives, assessed progress, and identified priorities for future interventions. Despite progress, improved recognition and prevention

of donor-derived transmission events is needed. It was concluded that this requires systems integration across the organ and tissue transplantation communities including organ procurement organizations, eye and tissue banks, and transplant infectious disease experts. Commitment of resources and improved coordination of efforts are required to develop essential tools to enhance safety for transplant recipients.

Likely Respondents: organ procurement organizations, tissue banks, eye banks

Total Estimated Annualized Burden - Hours

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
OPOs	17	1	85/60	24.1
Eye Banks	7	1	55/60	6.4
Total				30.5

Darius Taylor,

Information Collection Clearance Officer.

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